The Commonwealth of Massachusetts
HOUSE POST AUDIT AND OVERSIGHT BUREAU
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HOUSE POST AUDIT AND OVERSIGHT BUREAU

REVIEW: MEDICATION ADMINISTRATION

PROGRAM: DMH, DMR

JUNE 1998

MAP

The House Post Audit Bureau has been conducting an ongoing inquiry concerning the administration of medication to various persons under the care of the Department of Mental Health (DMH) and the Department of Mental Retardation (DMR). As documented in earlier Bureau reports on DMR and DMH investigations, the issues of oversight and monitoring of a decentralized system are complex and challenging. The Bureau reiterated earlier findings made in reports about DMH and DMR regarding problems with overseeing a decentralized system primarily for the purpose of establishing the threshold problems of oversight, but also as support for the notion that oversight of such a system is more difficult and more expensive.

The Bureau views the MAP program to be another facet of the oversight and monitoring element of our DMH and DMR systems. The principal question posed is whether each agency has the ability to monitor, oversee and minimize the levels of risk and danger associated with the administration of medication to the recipients of services of each agency.

Partly in response to concerns about medication administration and oversight the DMR Commissioner created the position of Assistant Commissioner for Quality Management. Among her responsibilities, is the implementation of an agency-wide risk management program which will encompass the medication administration program.

In addition to the provision of basic care and habilitative support, DMH and DMR oversee the administration of pharmaceuticals when part of an individual's plan of care. While, for the purposes of the MAP, the total number of clients from each agency has been grouped together, the Bureau notes at the outset distinct differences between DMH and DMR clients that require very different program structures and clinical approaches to the provision of services for each client group.

The DMH client base can be broadly described as follows:

1) DMH clients are generally mobile, have the right to refuse anti-psychotic medication (unless under court order, i.e. "Rogers" order), have the ability to self-

medicate in many cases and have the ability to understand the side effects of the medications taken. 80% of DMH's clients are subject to MAP.

2) DMH clients can be treated and self medication is considered a principal part of the management of the client's mental illness.

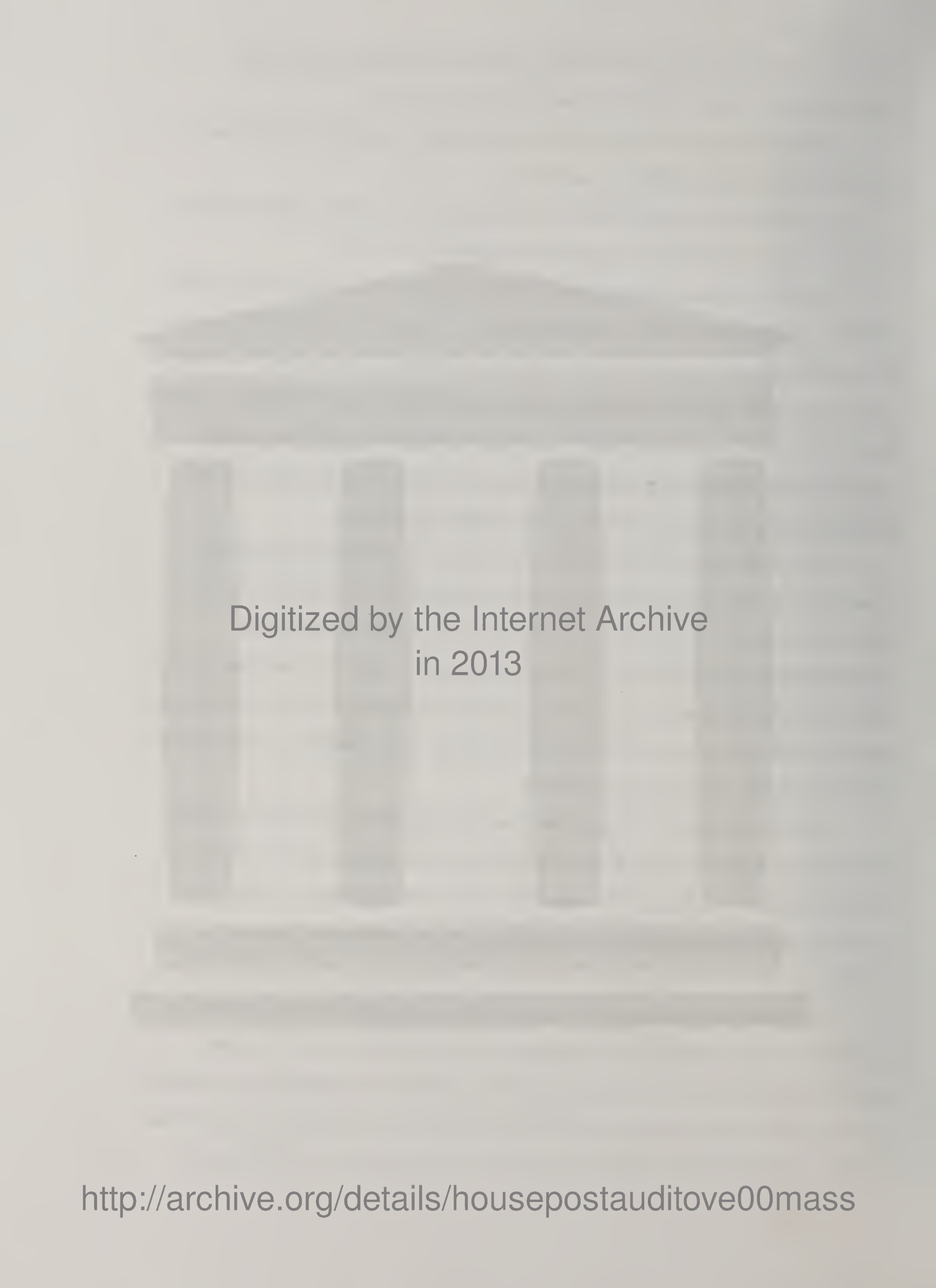
3) DMH clients, because of constitutional right and mobility, are more difficult to oversee and present different oversight issues from DMR clients.

4) DMR clients are generally more stable in terms of their clinical issues and in terms of the permanence of their residential setting. As a general matter, DMR clients have a greatly reduced capability to self medicate and generally do not have the ability to comprehend the full nature of adverse reactions or side effects from medications. 90% of DMR's clients (10% more than DMH's) are subject to MAP. By definition mental retardation is a condition requiring a level of support which varies depending on the individual and the current circumstances, but is generally life long.

The Bureau notes these major distinctions between clients primarily for the reason that they present very different oversight requirements. As a general matter, a DMR client is much more reliant on a highly structured system of medication administration than a DMH client. The Bureau recognizes, however, that although both DMH and DMR populations present with very different clinical profiles and professional oversight needs, the basic system for the administration of medication by unlicensed but certified staff share many common elements.

The Bureau would also note at the outset that both DMH and DMR have been extremely cooperative with the Bureau's inquiry and have been open to discussing potential problems candidly and constructively. The Bureau believes that this cooperation can only be positive in developing effective solutions to this complex problem.

The historical question of how the medication administration issue became so significant is only marginally relevant to the Bureau's inquiry. One obvious but significant factor has been the movement of many clients to community based settings as a result of the decrease in large, centralized DMH and DMR facilities over the past two decades. Administration of medication in small, community homes is dramatically



different from the centralized state facility system, which requires a large, highly structured and layered system overseen by licensed professionals and trained administrators.

Given the growing, decentralized community system, the Bureau has tried to define the parameters of this model and determine the appropriate level of licensed personnel involvement necessary to properly oversee the administration of medication. Although the Bureau agrees that the same basic system for administering medication can be utilized by both agencies, the issues of oversight are substantial and each agency must design its own professional oversight system to ensure that licensed professionals recognize and respond to the unique needs of the two client groups.

In the course of its review the Bureau conducted a broad range of inquiries. In addition to contacting other states, the Bureau also examined basic oversight and care provision issues. The Bureau examined pharmacy and distribution issues, licensing issues, as well as problems presented by different medication regimes and routes of administration, such as injectibles versus oral administration training of non-licensed personnel.

In addition, the Bureau reviewed the agency's' approach to managing data on actual medication errors and utilized the information derived from investigations into client abuse and client death. The Bureau also reviewed the hundreds of incident reports that were filed and kept by the agencies over the years.

Based upon the initial review the Bureau notes the following findings and identifies the following problem areas:

1) The administration of medication to DMH and DMR clients housed principally in a community based system is extremely complex. The needs of DMH and DMR clients are significantly different and although a single medication dispensing system may be acceptable for both agencies, a system for professional oversight is needed and should recognize that the needs of the clients of each agency are different.

2) The limited ability to place licensed personnel on all sites on an ongoing and regular basis has significant cost implications that represent one of the principal reasons why other states and Massachusetts have gone to systems where unlicensed but certified

individuals dispense medication. The appropriateness of administration by unlicensed personnel has been hotly contested especially in the context of particular settings. In particular, issues relating to administration to individuals with "G tubes", injectibles and complex antipsychotics have been major sources of conflict between agencies, recipients and licensed personnel.

3) The Bureau found that the data, to the extent it existed in uniform format, in all likelihood understated the number of errors and "occurrences" in the administration of medication Not only were reporting practices complicated, but issues such as staff turnover, confusion about what types of incidents constituted errors or occurrences that were required to be reported, underreporting and inability of staff to recognize an error, were all factors which contributed to the Bureau's finding that the number of errors was understated. On the other hand, the Bureau reviewed historical incident reports that were filed simply because of a lack of understanding of issues that were required to be reported. In several cases, multiple reports appeared to have been filed for the same "incident".

Prior to December 1, 1996, reporting of medication errors was accomplished manually. The old system had dual definitions - incidents and occurrences. Subtle distinctions here were generally lost among staff resulting in non-reporting or underreporting. With the advent of an automated reporting system in December of 1996, simplified forms and standard definitions were implemented. Prior to December 1, 1996, for example, medication refusals were documented as medication errors. Now DMH and DMR are reporting the same data to DPH on the same form. In addition, reporting was done in the aggregate rather than individually. It is also important to note that prior to the fall of 1996, DPH lacked a full-time registered nurse to coordinate the MAP program.

4) The Bureau found that as a general statement there was little incentive to report, especially to report "minor" occurrences. In addition to the issues raised in item number three, the Bureau found a system which had limited ability to detect underreporting of occurrences or medication errors.

5) The Bureau found that communications was a significant issue that affected the level of problems with MAP. The Bureau found instances where prescribing physicians failed to communicate dosage changes to either pharmacists or staff. Direct care workers did not always document issues or address concerns relative to side effects or changes in protocol. The Bureau was also made aware of language issues where prescriptions and directions on changes from physicians were not understood because of workers whose principal language was not English. While the original protocols were understood the changes were not communicated in the same language.

The Bureau also found historically that the level of medication errors may have been understated due to the following:

a) the inability to recognize problems by inadequately trained staff

b) the inability of DMH and DMR clients to communicate errors

c) the historical inability to properly and comprehensively investigate deaths (the Bureau notes specific improvements in both agencies here). See the House Post Audit and Oversight Bureau's report on DMR "Are You Sure About This Guy ?" and DMH "Death Investigation Report".

d) basic failures of the system of oversight because of a lack of attention to the complex nature of the decentralized service delivery system.

6) The Bureau had great concerns about the adequacy of training of personnel assigned responsibility for the administration of medication to clients. Given the low salaries and continuing problems with staff turnover, the Bureau has doubts about the long-term ability of these personnel to develop sufficient experience and expertise to identify serious side effects of medications on an ongoing basis. The Bureau's prior experience with turnover rates of DMR direct care workers does not give it reason for optimism in this regard. While the MAP has taken an aggressive approach to the training problem, the Bureau believes it is a concern that will require constant and vigilant attention.

7) The Bureau believes that the legal and liability issues relating to the program may be understated. The Bureau has concerns that simply placing nurses in positions of oversight of unlicensed personnel may result in direct liability for the particular nurse

who performs oversight in cases where serious errors occur. If for instance an LPN or RN identifies a continuing medication error by a technician, does it become the nurse's responsibility to oversee all subsequent follow-up? Where does the liability fall at that point if a problem results? Does a nurse performing an oversight function in an error situation result in a nurse/client relationship? There are questions which the Bureau believes need to be clearly addressed by the statutory scheme that governs nursing and the regulation of nurses must clearly identify the responsibilities and obligations of the nurse for this system to work.

The Bureau noted the particular concerns with the definition of nursing practice under MGL c.112 s.80B. "Nursing practice involves clinical decision-making leading to the development and implementation of a strategy of care to accomplish defined goals, the administration of medication...". Clearly the statutory scheme contemplates that nurses have significant responsibility for the administration of medication.

In the course of the Bureau's review, staff interviewed several nurses who had expressed deep concerns about providing "professional oversight" of certified but unlicensed medication administration personnel . In some cases nurses had chosen to seek alternative employment for fear that their license might be in jeopardy under the current MAP. The Bureau found a number of nurses who expressed specific concerns where an error was detected. If the nurse believed intervention was required, then at what point did follow-up and remediation fall squarely on the nurse, and did this oversight action result in a nurse/patient relationship?

Some of the concerns articulated by persons interviewed by the Bureau related more directly to quality of care and general oversight than to the medication issue. Several nurses also expressed concerns related to the potential for a number of cases to be ongoing and thereby establishing responsibility for more cases than would be practical to administer. However, for the first time, the Massachusetts Board of Registration in Nursing has endorsed the MAP program, largely because of the implementation of clinical oversight.

The bureau found that while the MAP program is not a nurse delegation model, DMH and DMR must be more clear and direct in their definition of the roles and

responsibilities of nurses in a professional oversight model. Clear lines of authority and communication are critical to the success of the program given the constraints already described.

Both DMH and DMR have requested increases in MAP funding for fiscal 1999. The most critical piece in the MAP improvement plan is the clinical oversight component. This feature must be implemented to ensure consistency and quality in the overall program operation. Currently, while area MAP coordinators are full-time DMH employees and are registered nurses, oversight staff are not all full-time. To illustrate, if DMR receives their requested budget increase, 70 plus FTE's will be added for MAP. DMH is seeking to add 59 new FTE's for MAP oversight. For DMH, this translates into one-half hour per patient per week of clinical oversight, or one staff meets with 80 patients per week.

In addition, the Bureau made specific findings of cases which indicated systemic problems with the current system.

1) Poor communication between prescribing physicians, medication administration personnel and pharmacists;

2) Cases where side effects from strong anti-psychotic medications were not detected;

3) Recurring problems with stockpiling of medications by some DMH clients;

4) Problems with clients with complex needs who receive moderate supervision and who can not advocate for themselves;

5) The inability on the part of staff to detect medication side effects.

The Bureau also reviewed the investigative files of the Conrad Simon case. The Bureau was unable to determine whether in fact the cause of death here was a medication error or something more serious. A review of the investigative files left substantial doubt as to the specific reason for the death.

In particular, the Bureau noted that the DPPC investigative report stated that "there was no discrepancy between the amount of pills on hand and the dosages given." Yet at the same time the Bureau also observed certain inconsistencies in the investigative report relating to this precise point. The Bureau notes that these statements appear

inconsistent with another witness's concerns with medication dosages indicated in the toxicology analysis and police report. The cause of death in the Medical Examiner's report was chlorpromazine intoxication from an acute overdose of Thorazine capsules.

The Bureau found this finding disturbing when viewed in the context that the decedent was unable to swallow pills and had to take medication that was crushed to a powder and mixed with pudding. With the current record, the Bureau is unable to reconcile the DPPC report findings with the statements in the toxicology report. Given the amount of medication found in the body (510 micro grams of Thorazine per deciliter, according to the toxicology report; the normal range being 1-50 micro grams per deciliter) as well as the fact that the decedent was unable to swallow pills, there were many more issues that needed to be resolved.

At the very least, either the decedent was capable of swallowing pills and did in fact overdose or somehow more medication than was prescribed found its way into the pudding - either by error or intent. Neither of these scenarios however, can be reconciled with the investigation's apparent finding that the "proper" amount of doses was found to be remaining in Simon's inventory. The Bureau finds the failure to reconcile these issues most troubling. At one point the report states the decedent: "was the healthiest of consumers...:" yet another witness interviewed said he was "not in best care, vascular shape, ...experienced shortness of breath after a walk up an incline...".

The report also noted no evidence of medications omitted or that the wrong dosage was given. The complexity of this case is reflected in the extended involvement of the Medical Examiner's office and their decision to obtain an independent review by a toxicology consultant to determine the cause of death. The Bureau found that it was not at all clear that this case presented a medication error. DMR should use the information gathered in the multiple reviews of this case to improve its oversight systems and to insure that other system failures are not confused with issues relating to administration of medications.

The Bureau was provided with the statistics for medication errors and/or occurrences by both DMH and DMR for 1996 and 1997. It is important to note that through the end of 1995, 75% of the medication error reports were not genuine

occurrences, according to DMH officials. Copies of those responses are attached as Exhibits I and II. The Bureau is engaged in an ongoing effort to monitor data files and statistics to verify and try to draw some conclusions about what is being reported.

As stated earlier, the principal problem area with MAP is the issue of oversight which is complex and difficult in a decentralized system. There is very little incentive on the part of workers or providers to report errors. Given historical problems with investigations it is difficult to gauge the magnitude of past evidence of problems in this area. The Bureau applauds the agency efforts to improve in this area, however the concerns about training, oversight and staff turnover are substantial ones and remain.

DMH and DMR must continue the recent efforts to minimize these problem areas and draw upon the expertise of others in providing medications in a home based environment. Based upon its review, the Bureau believes that both DMR and DMH are committed to making substantial improvements in the existing program. The commissioners of both agencies have been extremely open and cooperative in providing information about problems and attempts to correct them. The Bureau believes that given the effort and commitment of both agencies progress has already been made and will continue. The current issues that remain center around the level of cases that mandate administration by licensed clinicians, and the involvement and liability clinicians may have in any system where they provide oversight rather than direct action in terms of providing medication. The Bureau is encouraged by DMR's decision to obtain an independent evaluation of the issues related to the administration of insulin and of medications via gastrostomy tube.

The Bureau's review of other private care systems reveal problems with medication administration even in the hospital setting with licensed clinicians. The problems of complexity of mediations, poor communication between physician and nurse clinician and staff do not disappear simply because pharmaceuticals are administered in a hospital setting. Errors can and do occur. The key is to have a system that minimizes them and responds promptly and appropriately to their occurrence and consequences.

The problems of MAP are unquestionably more complex when put in the context of the types of clients overseen by DMH and DMR. Any system of MAP must recognize

the differences between these clients and a typical private or non-profit hospital setting. The Bureau notes however, that even in its other reviews of medication administration in a total clinical setting, errors did occur with unacceptable frequency. Issues of lack of communication, complexity of new pharmaceuticals, as well as sufficiency of staff issues all pointed to problems even in the hospital setting. The Bureau notes these issues to state clearly the complexity of the issues confronting both DMR and DMH.

The Bureau remains concerned that the fiscal constraints on the program may impact its implementation. If for example, clinical oversight on follow-up cases becomes extensive, will costs for more nursing staff continue to grow? The bureau is also concerned that staff turnover may require cost increases for both direct salaries and training. Finally, the logistics of administration and oversight in a large, decentralized system remain formidable. Both agencies must seek aggressive measures to achieve economies of scale and joint efforts wherever feasible and appropriate.

The Bureau believes that the MAP Improvement Plan put forth by DPH, DMH and DMR if fully funded will begin to address the majority of deficiency areas cited in this report, if implemented as described. The Bureau believes that along with the planned improvements, the agencies address the legal/liability issues which have been raised by nurses and noted by us in relation to professional oversight. Clear delineation of the roles and responsibilities of nurses involved in this activity is essential to the effective management of the administration of medication in DMH and DMR community homes.

The Bureau makes the following recommendations based upon its initial review:

1. That DPH establish a Quality Review Team, including MNA and the Professional Nurses Association to ensure the integrity of and the effective operation of the MAP program. This group should meet regularly with the affected agencies and commissioners to discuss planning and implementation issues.
2. DMH and DMR should agree to spot checks and inspections of the MAP program's operation by the quality review team and report findings to the House Post Audit and Oversight Committee and DPH.

3. DMH and DMR should agree to provide monthly progress reports on the MAP program to the House Post Audit and Oversight Committee.
4. The Conrad Simon case should be reinvestigated by the Disabled Persons Protection Commission to re-evaluate the inconsistency in information reported.

Conclusion

The Bureau remains concerned about the long term prospects for the MAP program. While no one group is satisfied with the current status, it is clear to the Bureau that the proposal before the Legislature represents a significant improvement. The oversight, training and turnover issues that confront the staff of this program are significant and long term. The Bureau believes however, that the current Commissioners and members of the Health Care Committee have demonstrated the kind of leadership and commitment necessary to make the program successful.

The fiscal impacts of the program remain in doubt. The Bureau believes that it and other interested parties must work cooperatively to ensure that the issues raised in this report continue to be addressed.

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March 5, 1998

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Dear Mr. Hammond:

I am writing in response to your request for information regarding the Medication Administration Program (MAP).

1. **A definition of the term "medication error" in the MAP program. Has this changed in 1994,'95,'96,'97?**

   The guidelines for reporting medication occurrences were revised in December, 1996, in recognition of the fact that extraneous and irrelevant information was being collected under the previous Medication Occurrence Reporting (MOR) system. The MOR system was first implemented when the Medication Administration Program (MAP) was operationalized in May, 1994. For instance, the original MOR system required staff to report refusals and other events which, in general, were beyond the control of and/or did not reflect on the competence of MAP certified staff, e.g. three pills rolling under the refrigerator during an administration. In addition, there was considerable ambiguity with regard to the definition of a medication "error." Specifically, occurrences were classified as being either "incidents" or "errors" based upon a determination of their "potential for harm." This proved to be far too subjective to be either useful or meaningful, and resulted in inconsistent reporting among staff and providers. The pre-1996 system also was not amenable to tracking via a database, primarily because it depended heavily on written narratives by certified staff and supervisors.

The revised (MOR) system captures only occurrences and significant events related to administration of medication in a manner inconsistent with the prescribing practitioner's order, i.e., right dose, right time, right medication, right person or right route (commonly referred to as the 5 Rs). Thus, misadministrations (any breach of the 5 Rs) are no longer categorized as incidents or errors; all are classified as occurrences. In addition, any occurrence which results in medical intervention, illness, injury or death must be reported by telephone to a hotline maintained by DPH within 24 hours. This mandated reporting approach accomplishes, by eliminating the need to categorize occurrences subjectively as incidents or errors, what the pre-December 1996 system of classification failed to provide: namely, the ready identification of those occurrences causing, or with the greatest potential for causing, harm.

The revised MOR system also requires that a professional consultant be contacted for each and every occurrence to provide recommendations on appropriate action as well as technical assistance and advise to certified staff. The consultant must be available to staff 24 hours a day, 7 days a week. Defined by regulation, the individual must be a registered nurse, registered pharmacist or practitioner licensed to prescribe controlled substances. Finally, the revised MOR form has been re-formatted so as to make data entry and retrieval simple, thereby allowing ready access to the information for analysis.

2. **A complete description of the categories of reporting required where there is a medication error. This would include a description of how the following events have been classified.**

As noted above, any breach of the 5Rs results in the filing of an MOR, with the further requirement that DPH be notified within 24 hours of occurrences of a potentially more serious nature. All occurrences are entered into the MOR database according to which breach of the 5Rs was involved. Missed doses resulting from factors beyond the control of certified staff, e.g., client refusals, while of clinical significance, do not require an MOR but rather are documented in the consumer's record. However, doses missed because staff simply "forget" or because the medication was unavailable are reported via an MOR.

3. **A listing and description of all reporting systems, data systems, data bases, notification for all medication errors, medication occurrences.**

All MORs are forwarded to Area/Regional MAP Coordinators by state-operated or contracted providers within 7 days, including those which have already been reported to DPH under the 24 hour reporting requirement. The MORs are then reviewed by the respective Area/Regional Coordinators and appropriate follow-

up initiated, as indicated. The information contained on the MOR, including the provider agency, site location, type of occurrence, consultant contact, whether medical intervention or harm resulted, and contributing factors is entered into a centralized database maintained by DMH. Reports of the aggregate data are generated on a quarterly or as needed basis and provided to DPH, as is the raw data itself. Finally, all MORs are forwarded to DPH where they receive further review and follow-up.

4. **All data that has been compiled to determine medication errors for 1996, 1997.**

   Summary information of MOR data for 1996 and 1997 is attached. As you will note, there were more than 24,000 MORs for 1996, and over 1790 for 1997. Redacted copies or a random sample of redacted copies will be provided upon request. Given the volume, a reasonable timeframe in which to comply is requested. I will call to discuss the transmittal process with you.

As you know, we are working with the Joint Committee on Health Care on a plan to improve MAP. The plan currently before the Health Care Committee will strengthen the role of nursing in some residential programs, improve the curriculum and testing program, and strengthen the state's oversight function. We believe this plan will improve the care and safety of clients living in our residential programs.

I would be pleased to provide any additional information or explanation as you deem appropriate.

Sincerely,

Marylou Sudders

Marylou Sudders

attachment

DMH
Medication Occurrence Report ("MOR")
Summary

Period Covered: 01/01/97 - 12/31/97

Total # MORs Submitted: 1877

Date of Report: 04/28/98

TYPE OF OCCURRENCE	COUNT	% OF TOTAL
Wrong Time	1187	63
Wrong Dose	581	31
Wrong Medication	115	6
Wrong Individual	44	2
Wrong Route	2	-
Unknown or Unspecified	14	-
RECOMMENDED ACTION(S)		
None	1787	95
Lab Work/Other Tests	7	-
Physician Visit	11	-
Clinic Visit	1	-
Emergency Room Visit	16	-
Hospitalization	3	-
Other[1] *(see note below)*	88	5
RESULT(S)		
Medical Intervention	23	1
Illness	1	-
Injury	0	-
Death	0	-
CONTRIBUTING FACTOR(S)		
Failure to Accurately Record or Transcribe Order	181	10
Failure to Properly Document Administration	57	3
Medication Administered By Non-Certified Staff	15	-
Medication Had Been Discontinued	51	3
Improperly Labeled By Pharmacy	41	2
Medication Not Available	312	17
None	1253	67

[1] includes such "interventions" as withholding medication secondary to physician/consultant recommendation, speaking with consultant, etc., which program staff mistakenly note as "medical intervention" on MOR. As program staff became familiar with the 12/96 revision of the MOR form itself as well as the new reporting requirements, this problem was eliminated. Could technically be included in "None" category. NAME = MORTOT.DOC

1996*
Department of Mental Health
Medication Occurrence Report ("MOR")
Statewide Totals

	Errors	Incidents	Refusals	Total
Metro Boston	308	3428	4338	8074
Metro South	197	391	449	1037
Metro West	126	644	603	1373
Central Mass	412	1985	2780	5177
Northeast	1632	682	3920	6234
Southeastern	175	507	832	1514
Western Mass	218	574	493	1285
Total	3068	8211	13415	24694

Definitions

ERROR - limited to those occurrences involving breaches of the "5 'R's", i.e., Right client, Right medication, Right dose, Right time (*including complete omissions* ***other than refusals or because consumer was not present***), Right route.

INCIDENT - occurrences reported under regulations governing controlled substances, consumers failing to take pre-packaged medications, *doses omitted because consumer was not present*, doses withheld or given at other than the prescribed time per program's clinical protocol, documentation issue, lost/wasted medication, medication unavailable, improper label and any occurrence not otherwise classified as either an Error or Refusal.

REFUSAL - includes both active and passive instances, e.g., outright refusal or failure to respond to staff prompts.

**period covered is 11 calendar months, from January 1996 through November 1996. New MOR reporting/tracking format was implemented on December 1, 1996*

MOR1996.DOC

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March 9, 1998

Thomas W. Hammond
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Boston, MA. 02133-1053

Dear Mr. ~~Hammond~~ Tom:

The following information is submitted in response to your request for information regarding the Medication Administration Program (MAP).

1. **A definition of the term "medication error" in the MAP program. Has this changed in 1994, '95, '96, '97?**

The guidelines for reporting medication occurrences were revised in December, 1996 in response to concerns with the original system. The MOR system was first implemented when the Medication Administration Program (MAP) was operationalized in May of 1994. The 1996 changes came about because the original MOR system required staff to report refusals and other events which in general, were beyond the control of and/or did not reflect on the competence of the MAP certified staff, e.g. pills being dropped and rolling under the refrigerator during an administration was counted as a medication error under the previous MOR system even though the individual still received the prescribed medication. In addition, there was a lack of clarity with regard to the definition of a medication "error." Occurrences were being classified as "incidents" or "errors" based upon a determination of their "potential for harm." This proved to be far too subjective to be either useful or meaningful, and resulted in inconsistent reporting among staff and providers. The pre-1996 system also was not amenable to tracking via a database, primarily because it depended heavily on written narratives by certified staff and

supervisors. The revised MOR system now appropriately captures only those occurrences and significant events where medication is administered in a manner inconsistent with the prescribing practitioner's order, i.e., right dose, right time, right medication, right person or right route (commonly referred to as the 5 Rs). Thus, any breach of the 5 Rs are no longer categorized as incidents or errors; all are reported as occurrences. In addition, any occurrence which results in medical intervention, illness, injury or death must be reported by telephone to a hotline maintained by DPH within 24 hours. By eliminating the pre-December 1996 MOR requirement of categorizing occurrences as incidents or errors, this revised mandated report approach provides for ready identification of those occurrences causing, or with the greatest potential for causing, harm.

The revised MOR system also requires that a professional consultant be contacted for each and every occurrence to provide recommendations on appropriate action as well as technical assistance and advice to certified staff. The consultant must be available to staff 24 hours a day, 7 days a week. Defined by regulation, the individual must be a registered nurse, registered pharmacist or practitioner licensed to prescribe controlled substances. Finally, the revised MOR form has been re-formatted so as to make data entry and retrieval simple, thereby allowing ready access to the information for analysis.

2. **A complete description of the categories of reporting required where there is a medication error. This would include a description of how the following events have been classified.**

As noted above, any breach of the 5 Rs results in the filing of an MOR, with the further requirement that DPH be notified within 24 hours of occurrences of a potentially more serious nature, (those which require medical intervention and/or result in injury, illness or death). All occurrences are entered into the MOR database according to which breach of the 5 Rs was involved. Missed doses resulting from factors beyond the control of certified staff, e.g., client refusals, while of clinical significance, do not require an MOR but rather are documented in the consumer's record. However, doses missed because staff simply "forgot" or because the medication was unavailable are reported via an MOR.

3. **A listing and description of all reporting systems, data systems, data bases, notification for all medication errors, medication occurrences.**

All MORs are forwarded to Regional MAP Coordinators by state-operated or contracted providers within 7 days, including those

which have already been reported to DPH under the 24 hour reporting requirement. The MORs are then reviewed by the respective Regional Coordinators and appropriate follow-up initiated, as indicated. The information contained on the MOR, including the provider agency, site location, type of occurrence, consultant contact, whether medical intervention or harm resulted, and contributing factors is entered into a centralized database. Reports of the aggregate data are generated on a quarterly or as needed basis and provided to DPH, as is the raw data itself. Finally, all MORs are forwarded to DPH where they receive further review and follow-up.

4. **All data that has been compiled to determine medication errors for 1996, 1997.**

   Summary information of Medication Occurrence Reporting data for 1996 and 1997 is attached. As you will note, there were more than 2,852 reports for 1996, and over 2,165 for 1997. We will provide redacted copies or a random sample of redacted copies if you wish, or, as we discussed, arrange for an on-site review of the information, with DMR staff available to provide any assistance necessary to your process.

We take very seriously our responsibility to provide the level of clinical oversight and control appropriate to MAP's place in our broader system of health care provision. We want to continue our work with the Joint Committee on Health Care to strengthen the role of nursing and improve the testing, training and oversight components. The reporting system for medication occurrences has improved but we need to be diligent in our efforts to strengthen this critical link in the oversight system. We have most of the other necessary elements in place within the MAP and in the oversight functions of our certification, investigations and operational divisions, but we need to ensure the presence of and adherence to a safe and comprehensive system for administering medications to people served by our Department.

I would be pleased to provide any additional information that might be helpful in your review.

Sincerely,

Gerald J. Morrissey, Jr.
Commissioner

Department of Mental Retardation
1996
Medication Occurrence Report ("MOR")
Statewide Totals

	Errors	Incidents	Refusals	Total
Region I	295	268	0	563
Region II	86	491	129	706
Region III	245	272	51	568
Region V	101	15	7	123
Region VI	288	556	48	892
TOTAL	1,015	1,602	235	2,852*

Definitions

ERROR - limited to those occurrences involving breaches of the "5 'R's", i.e., Right client, Right medication, Right dose, Right time (including complete omissions other than refusals or because consumer was not present), Right route.

INCIDENT - occurrences reported under regulations governing controlled substances, consumers failing to take pre-packaged medication, doses omitted because consumer was not present, doses withheld or given at other than the prescribed time per program's clinical protocol, documentation issue, lost/wasted medication, medication unavailable, improper label and any occurrence not otherwise classified as either an Error or Refusal.

REFUSAL - includes both active and passive instances, e.g., outright refusal or failure to respond to staff prompts.

*Numbers based on reports from Regional MAP Coordinators

DMR
Medication Occurrence Report ("MOR")
Summary

Period Covered: 01/01/97 - 12/31/97

Total # MORs Submitted: 2165

Date of Report: 01/30/98

TYPE OF OCCURRENCE	COUNT	% OF TOTAL
Wrong Time	1432	66%
Wrong Dose	530	24%
Wrong Medication	132	6%
Wrong Individual	68	3%
Wrong Route	3	-
Unknown or Unspecified		
RECOMMENDED ACTION(S)		
None	2066	98%
Lab Work/Other Tests	12	less than 1%
Physician Visit	3	less than 1%
Clinic Visit	1	-
Emergency Room Visit	5	less than 1%
Hospitalization	1	-
Other[1] *(see note below)*	12	less than 1%
RESULT(S)		
Medical Intervention	19	less than 1%
Illness	1	-
Injury	0	0
Death	0	0
CONTRIBUTING FACTORS		
Failure to Accurately Record or Transcribe Order	186	9%
Failure to Properly Document Administration	136	6%
Medication Administered By Non-Certified Staff	32	1%
Medication Had Been Discontinued	56	3%
Improperly Labeled By Pharmacy	39	2%
Medication Not Available	114	5%
None	1580	74%

[1] includes such "interventions" as withholding medication secondary to physician/consultant recommendation, speaking with consultant, etc., which program staff mistakenly note as "medical intervention" on MOR. As program staff became familiar with the 12/96 revision of the MOR form itself as well as the new reporting requirements, this problem was eliminated. Could technically be included in "None" category. NAME = MORTOT.DOC

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DMR
Medication Occurrence Report ("MOR")
Summary

Period Covered: 01/01/97 - 04/28/98

Total # MORs Submitted: 3164

Date of Report: 06/12/98

TYPE OF OCCURRENCE	COUNT	% OF TOTAL
Wrong Time	2162	68%
Wrong Dose	728	23%
Wrong Medication	173	5%
Wrong Individual	96	3%
Wrong Route	5	LESS THAN 1%
Unknown or Unspecified		
RECOMMENDED ACTION(S)		
None	3002	98%
Lab Work/Other Tests	37	1%
Physician Visit	3	less than 1%
Clinic Visit	1	less than 1%
Emergency Room Visit	13	less than 1%
Hospitalization	2	less than 1%
Other[1] (see note below)	13	less than 1%
RESULT(S)		
Medical Intervention	46	2%
Illness	4	less than 1%
Injury	5	less than 1%
Death	0	-
CONTRIBUTING FACTORS		
Failure to Accurately Record or Transcribe Order	358	11%
Failure to Properly Document Administration	195	6%
Medication Administered by Non-Certified Staff	34	1%
Medication Had Been Discontinued	64	2%
Improperly Labeled By Pharmacy	51	2%
Medication Not Available	193	6%
None	2234	71%

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